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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
FIERRO, ALICIA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/587,330

Applicant(s)

JONES ET AL.

Examiner

Alicia L. Fierro

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-16 are pending in the current application, filed July 27, 2006. This application is a national stage entry of International Application No. PCT/US2005/002472, filed January 26, 2005, which claims priority to U.S. Provisional Application No. 60/540,538, filed January 30, 2004.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I: Claim(s) 1-13 and 16, in part, drawn to various compounds of Formula (I) wherein R1 is a moiety *not* containing HetB or HetC, compositions, and pharmaceutical combinations thereof.
- Group II: Claim(s) 1-13 and 16, in part, drawn to various compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 544 (i.e. six-membered heterocyclic rings with at least 2 heteroatoms, at least one being nitrogen), compositions, and pharmaceutical combinations thereof.

- Group III: Claim(s) 1-13 and 16, in part, drawn to various compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 546 (i.e. six-membered heterocyclic rings with one nitrogen), compositions, and pharmaceutical combinations thereof.
- Group IV: Claim(s) 1-13 and 16, in part, drawn to various compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 548 (i.e. five-membered heterocyclic rings with at least one nitrogen), compositions, and pharmaceutical combinations thereof.
- Group V: Claim(s) 1-13 and 16, in part, drawn to various compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 549 (i.e. sulfur or oxygen-containing heterocyclic rings with no nitrogen ring members), compositions, and pharmaceutical combinations thereof.
- Group VI: Claim(s) 14 and 15, in part, drawn to methods of using compounds of Formula (I) wherein R1 is a moiety *not* containing HetB or HetC, compositions, and pharmaceutical combinations thereof.
- Group VII: Claim(s) 14 and 15, in part, drawn to methods of using compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 544 (i.e. six-

membered heterocyclic rings with at least 2 heteroatoms, at least one being nitrogen), compositions, and pharmaceutical combinations thereof.

Group VIII: Claim(s) 14 and 15, in part, drawn to methods of using compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 546 (i.e. six-membered heterocyclic rings with one nitrogen), compositions, and pharmaceutical combinations thereof.

Group IX: Claim(s) 14 and 15, in part, drawn to methods of using compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 548 (i.e. five-membered heterocyclic rings with at least one nitrogen), compositions, and pharmaceutical combinations thereof.

Group X: Claim(s) 14 and 15, in part, drawn to methods of using compounds of Formula (I) wherein R1 is a moiety containing HetB or HetC (i.e. substituents (8), (9), (10), (11) and (13)), wherein the HetB or HetC ring is classified in class 549 (i.e. sulfur or oxygen-containing heterocyclic rings with no nitrogen ring members), compositions, and pharmaceutical combinations thereof.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), “the international application shall relate to one invention only or to a group of inventions.” Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied “where a group of inventions is claimed in one and the same international application, the requirement of unity referred to in Rule 13.1 shall be

fulfilled only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.”

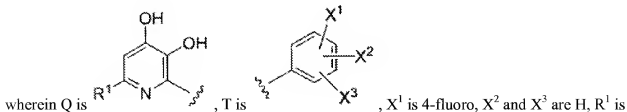
3. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art so linked as to form a single general inventive concept. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking the claims is the structure of Formula (I), as defined in claim 1, which is shared by all instant claims. Prior art exists which causes the core structure in the instant application to lack a special technical feature. Obvious variants of this structure have been seen in numerous patents and papers. For example, US 2005/0176767 (which claims priority to U.S. Provisional Application No. 60/515,443, filed 10/20/03) teaches several examples of obvious variants of the compound claimed in instant claim 1. One example is taught as Example 5 on p. 16 of the specification of the ‘767 publication and is as follows:

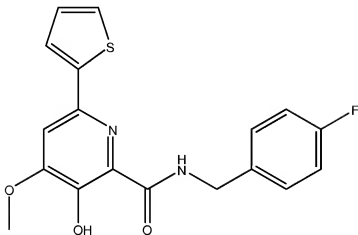
EXAMPLE 5

3-Hydroxy-4-methoxy-6-thiophen-2-yl-pyridine-2-carboxylic acid 4-fluorobenzylamide compound 16

This compound is of the following structure, and corresponds to a compound of Formula (I)



HetB wherein HetB is a thiophene ring:



The only difference between the compound taught by the '767 publication and the instantly claimed compounds is a substitution of hydrogen for the methyl group one the oxygen at the 4-position of the pyridine ring. Hydrogen and methyl substitutions are known in the art and are deemed to be obvious variants of each other. *In re Wood*, 199 USPQ 137. Thus, replacing the methyl with a hydrogen at the 4 position of the pyridine ring is an obvious variation of the known compound. Therefore, the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Accordingly, Groups I-X are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. As an additional requirement, with the election of any of **Groups I-X**, an election of species of a particular compound is also required. In order for this election to be considered fully responsive to this requirement, the election **must include**:

Groups I-X:

- a) the **name** and **structure** of one particular species of the instantly claimed compound of Formula (I),
- b) the **location** of the species (a) within the claims or (b) within the specification,
- c) the **claims** that read on the elected species,
- d) a **definition** of the exact substitutions,
e.g. R₁ is hydrogen, X is oxygen, etc...

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the structure of the generic compound fails to overcome that of the prior art, namely US 2005/0176767, for reasons discussed in the restriction requirement above. Additionally, for example, a compound of Formula I wherein R1 is C1-6 fluoroalkyl is structurally different than and distinct from a compound of Formula I wherein R1 is HetB (a 5-6 membered heteroaromatic ring), for example. Therefore, these two compounds are different species or lack the same core structure or special technical feature.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday-Thursday 6:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia L. Fierro/
Examiner, Art Unit 1626

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626